

employed to assess the effects of interventions, such as exercise, pacing, and drugs.

Measurement of systolic time intervals offered promise of becoming useful for serial study of left ventricular function, in patients in the coronary care unit after myocardial infarction, and in post-operative patients after coronary artery surgery. However, in both these areas, results have been conflicting.

How readily can these data be obtained? Reliable systolic time intervals can be recorded by any physician who has ready access to a high-quality multi-channel phonocardiograph, performs the technique frequently, is careful to assure high quality electrocardiogram, phonocardiogram and pulse tracings, has the time and patience to make accurate measurements, and understands the limitations of the method.

Can systolic time interval measurement ever substitute for cardiac catheterization to yield information that is not apparent from the history, physical examination, ECG and chest x-ray films? For a decade or more, the systolic time interval technique gained little acceptance and was not utilized by most cardiologists. As the need to evaluate left ventricular function increased, systolic time intervals became more popular. Unfortunately, the technique was frequently employed in a manner which its originators would deplore.

Measurement of systolic time intervals seldom yields data that surprise the experienced cardiologist. When considered in context, such measurements may supply useful information. Moreover, they have two cardinal virtues:

1. They can be performed repeatedly with no danger, little or no discomfort, and little expense to the patient; and
2. The results are quantitative. Thus, serial changes can be detected readily. Accordingly, measurement of systolic time intervals is likely to play an increasingly role in clinical cardiology and deserves continued energetic research effort.

Selected Items from the FDA Drug Bulletin

Intrauterine Devices

Precautions During Use

THE FOOD AND DRUG ADMINISTRATION wishes to inform physicians that intrauterine devices (IUDs), being used by more than three million women in the United States for birth control, have not been subjected to premarket review by the FDA. Because of growing concern about the safety of some of these products, information from FDA files is presented here for physicians.

The mechanism of action of IUDs is not precisely known, but it is generally recognized to be dependent upon the foreign body reaction produced by them.

Sterile technique should be used in inserting an IUD. It should not be introduced in women who are pregnant, have a history of infected abortion or postpartum endometritis within the previous six weeks, have acute or subacute pelvic inflammatory disease, acute cervicitis, distortion of the uterine cavity due to myomas, or a recent history of abnormal uterine bleeding, or who have suspected uterine malignancy. Incidence of perforation on insertion is higher when insertion is performed early postpartum.

An estimated 10 percent of IUDs are expelled during the first year after insertion. Expulsion is more frequent among younger women and usually occurs during menses.

The pregnancy rate for each type of IUD has not been precisely determined. However, for the most successful types the rate is 1.5 to 3 pregnancies per 100 woman-years during the first year and lower thereafter. These devices are less effective than conventional oral contraceptives (0.3 to 0.5 pregnancies per 100 woman-years), but they are generally considered to be more effective than other mechanical methods of contraception.

There is no evidence that ectopic pregnancies are caused by IUDs. However, since IUDs markedly reduce the incidence of intrauterine but not ectopic pregnancies, the ratio of intrauterine to ectopic pregnancies is altered. No relationship between IUDs and premature or malformed offspring has been established although such incidents have been reported.

Major adverse reactions include excessive bleeding, pelvic inflammatory disease, imbedment, and perforation of the uterus. Abdominal perforation by a closed IUD may result in herniation of tissue through the closed loop. Therefore, a closed IUD should be promptly removed surgically when the diagnosis of perforation is made. Removal of an open device is optional depending upon the clinical situation.

Among less serious adverse reactions associated with IUDs are irregular bleeding, uterine cramps, pelvic pain, and backache.

FDA has received numerous reports of serious reactions associated with an IUD known as the Majzlin Spring. The danger of the device imbedding in the walls of the uterus increases the longer it is left in place. FDA is taking this opportunity to notify physicians directly about this hazard and is urging women using the Majzlin Spring to contact their physicians so that it may be removed as soon as practicable.

FDA's Obstetrics and Gynecology Advisory Committee prepared a detailed report in 1968 on experience with the marketed IUDs and FDA is undertaking another intensive review of all IUDs currently on the market. Proposed legislation has been introduced into Congress which would authorize FDA to establish appropriate controls for these devices. FDA believes at the present time that the IUD is an acceptable method of contraception which can be employed safely and effectively providing adequate precautionary measures are observed.

FDA Drug Bulletin, August 1973

Poison Prevention Packaging for Drugs

UNDER A LAW ENACTED in 1970, hazardous substances that may cause serious illness or injury in young children must be dispensed in child-resistant containers. In addition to safety caps the approved packaging may include any container which is suf-

ficiently difficult for children to open. For example, unit packaging which requires the child to repeat the opening operation for each dosage unit may qualify.

Aspirin, except as an ingredient of powders and certain effervescent preparations, was the first drug to be so regulated. Next are all oral prescription drugs as of April 1974. An exception to this regulation is nitroglycerin, which must be readily available for emergency use by the elderly and must be dispensed in its original, sealed packet. Other exemption possibilities are under consideration.

The physician or consumer may request conventional packaging for any of the regulated drugs.

Additional over-the-counter drugs which pose accidental poisoning hazards to children under the age of five years are under consideration for safety packaging requirements.

FDA Drug Bulletin, August 1973

AMA Placement Service

The AMA's Physicians' Placement Service, which last year helped place an estimated 200 physicians, will exhibit at the AMA Clinical Convention in Anaheim. The meeting will run from December 1 through 5. The Service's 2,500 active physician resumés and listings of an equal number of openings will be available for the use of convention attendees at the Anaheim Convention Center. Included on Placement Service files are all specialties and most subspecialties covering all areas of the United States and some foreign locations.

The AMA Placement Service is free of charge to all registrants. Close association with placement services operated by state medical associations provides for wide circulation of physicians' resumés.

For additional information write the Physicians' Placement Service, American Medical Association, 535 North Dearborn Street, Chicago, Illinois, 60610.